



PTO/SB/08a

Approved for use through 07/31/2008. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

1

of

2

Complete if Known

Application Number	10/717,925
Filing Date	November 21, 2003
First Named Inventor	William J. Carroll
Art Unit	3762
Examiner Name	Unknown
Attorney Docket Number	000309.00051

U. S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

**Examiner
Signature**

S. G.

**Date
Considered**

1/20/06

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



TO/SB/08b (08-03)

Approved for use through 06/30/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/717,925
Filing Date	November 21, 2003
First Named Inventor	William J. Carroll
Art Unit	3762
Examiner Name	Unknown

Sheet 2 of 2 Attorney Docket Number 000309.00051

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
S G		MOHAMED A. HAMZA, M.D., et al., Effect of the Duration of Electrical Stimulation on the Analgesic Response in Patients with Low Back Pain, Anesthesiology, December 1999, pp. 1622-1627, Vol. 91, No. 6	
		EL-SAYED A. GHONAME, M.D., et al., The Effect of Stimulus Frequency on the Analgesic Response to Percutaneous Electrical Nerve Stimulation in Patients with Chronic Low Back Pain, Anesthesia & Analgesia, April 1999, pp. 841-846, Vol. 88, No. 4	
		RICHARD E. SEROUSSI, MD, et al., Effectiveness of Percutaneous Neuromodulation Therapy for Patients with Chronic and Severe Low Back Pain, 2003, pp. 22-30, Vol. 3, Issue 1, Pain Practice	
		EL-SAYED A. CHONAME, MD, et al., Percutaneous Electrical Nerve Stimulation for Low Back Pain, JAMA, March 3, 1999, Vol. 281, No. 9	
		ANDREW J. ROBINSON, Clinical Electrophysiology, Electrotherapy and Electrophysiologic Testing, pp. cover, 285, 288-290, Second Edition, Williams & Wilkins	
		M.I. JOHNSON, et al., An in-depth study of long-term users of transcutaneous electrical nerve stimulation (TENS). Implications for clinical use of TENS, Pain 41, 1991, pp. 221-229, Elsevier Science Publishers B.V.	
		J.S. HAN, et al., Effect of low- and high-frequency TENS on Met-enkephalin-Arg-Phe and dynorphin A immunoreactivity in human lumbar CSF, 1991, pp. 295-298, Elsevier Science Publishers B.V.	
		ROGER M. NELSON, et al., Clinical Electrotherapy, third edition, Appleton & Lange, Stamford, Connecticut	
		Vertis Percutaneous Neuromodulation Therapy (PNT), Peer Review Network, Inc., PRN Newsletter, November 2002, Vol. 9, No. 6, pp. 1-5	
		PRIYA GOPALKRISHNAN, MS, et al., Effect of Varying Frequency, Intensity, and Pulse Duration of Transcutaneous Electrical Nerve Stimulation on Primary Hyperalgesia in Inflamed Rats, Arch Phys Med Rehabil, Vol. 81, July 2000, pp. 984-990	
		M.I. JOHNSON, et al., Analgesic effects of different frequencies of transcutaneous electrical nerve stimulation on cold-induced pain in normal subjects, Pain 39 (1989), pp. 231-236, Elsevier Science Publishers B.V.	
✓		SERGE MARCHAND, M.Sc., et al., Modulation of Heat Pain Perception by High Frequency Transcutaneous Electrical Nerve Stimulation (TENS), The Clinical Journal of Pain, Vol. 7, No. 2, 1991, pp. 122-129	

Examiner Signature

S. G.

Date Considered

1/30/06

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.
 This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PTO/SB/08a

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
on a collection of information unless it contains a valid OMB control number.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3 Attorney Docket Number 000309.00051

Complete if Known

Application Number	10/717,925
Filing Date	November 21, 2003
First Named Inventor	William J. Carroll
Art Unit	3762
Examiner Name	Unknown
Attorney Docket Number	000309 00051

Sheet 1 of 3

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
<i>SP</i>		US-6,647,296	11/11/2003	Fischell et al.	
	US-				

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
SQ		PCT/US03/37372 International Search Report	11/21/2003	International Rehabilitative Sciences, Inc.		

"EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 608. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 801.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



TO/SB/08b (08-03)

Approved for use through 08/30/2008. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

2

of

3

Complete if Known

Application Number	10/717,925
Filing Date	November 21, 2003
First Named Inventor	William J. Carroll
Art Unit	3762
Examiner Name	Unknown

Attorney Docket Number 000309.00051

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
S6		KATAYAMA Y., Deep brain stimulation therapy for involuntary movements, Rinsho Shinkeigaku, 2001/12/01 00:00; 41(12):1079-80, 1 page	
1		BENABID AL, et al., Deep btrai stimulation of the corpus luisi (subthalamic nucleus) and other targets in Parkinson's disease. Extension to new indications such as dystonia and epilepsy. J. Neurol. 2001/09/01 00:00; 248 Suppl 3:III37-47, 2 pages	
		ALLERT N., et al., Effects of bilateral pallidal or subthalamic stimulation on gait in advanced Parkinson's disease, Mov Disord. 2001/11/01 00:00; 16(6):1076-85, 2 pages	
		UTTI RJ, et al., Extended Follow-up of Unilateral Deep Brain Stimulation for Tremor, Deep brain stimulation remains an effective treatment for tremor for at least 3 years, according to this article, P03.1123; A220-221	
		OBWEGESER AA, et al., Quantitative and qualitative outcome measures after thalamic deep brain stimulation to treat disabling tremors, Neurosurgery, 48(2): 274-81, discussion 281-4 2001, 2-page Article	
		OBWEGESER AA, et al., Simultaneous thalamic deep brain stimulation and implantable cardioverter-defibrillator, Mayo Clin Proc, 76(1): 87-9, 2001, 2-page Abstract	
		OBWEGESER AA, et al., Thalamic stimulation for the treatment of midline tremors in essential tremor patients, Nekurology, 54(12): 2342-4 2000, 2-page Abstract	
		OH MY, et al., Deep brain stimulator electrodes used for lesioning: proof of principle, Neurosurgery, 2001/08/01 00:00; 49(2): 363-7; discussion 367-9, 2-page Article	
		RACETTE BA, et al., Thalamic stimulation for primary writing tremor, J Neurol. 2001/05/01 00:00; 248(5): 380-2, 2-page Report	
✓		ROCCHI L, et al, Effects of deep brain stimulation and levodopa on postural sway in Parkinson's disease, J. Neuro Neurosurg Psychiatry, 2002 Sep; 73(3):267-74, 2-page Article	

Examiner Signature

S - 6.

Date Considered

1 | 30 | 26

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



Approved for use through 06/30/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/717,925
Filing Date	November 21, 2003
First Named Inventor	William J. Carroll
Art Unit	3762
Examiner Name	Unknown

Sheet

3

of

3

Attorney Docket Number

000309.00051

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SF		NASSER JA, et al. Deep brain stimulation of VIM thalamic nucleus for tremor control, Arq Neuropsiquiatr. 2002 Jun; 60(2-B):429-34, 1-page Article	
1		RACETTE BA, et al., Ipsilateral thalamic stimulation after thalamotomy for essential tremor. A case report., Stereotact Funct Neurosurg. 2000/01/01 00:00; 75(4): 155-9, 2-page Article	
		RERZAI AR, et al., Neurostimulation systems for deep brain stimulation: in vitro evaluation of magnetic resonance imaging-related heating at 1.5 tesla, J Magn Reson Imaging, 2002/03/01 00:00; 15(3):241-50, 2-page Article	
		MAYA PINES, New Imaging Techniques That Show the Brain at Work: Brain Scans That Spy on the Senses, Seeing, Hearing, and Smelling the World, A Report from the Howard Hughes Medical Institute, 2-page Article	
		MAYA PINES, New Imaging Techniques That Show the Brain at Work: The Next Generation of Brain Scans, Seeing, Hearing, and Smelling the World, A Report from the Howard Hughes Medical Institute, 2-page Article	
		Oregon Imaging Article, P.E.T. Scan - Patient Information, 2 page Article	
		CIGNA CORPORATION, Positron Emission Tomography (PET) Scans - Medical Coverage, All States, 1999, 7-page Article	
		REZAI AR, et al., Neurostimulation systems for deep brain stimulation: in vitro evaluation of magnetic resonance imaging-related heating at 1.5 tesla, J magn Reson Imaging, 2002/03/01 00:00; 15(3):241-50, 2-page Article	
		MOBILE PET SYSTEMS, INC., Clinical Applications, 5-pages	
V		NEUROLOGICAL ASSOCIATES, INC., Deep Brain Stimulation, West Virginia, 6-page Article	

Examiner Signature

S - G.

Date Considered

1/30/06

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.